IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC.,
PELVIC REPAIR SYSTEM
PRODUCTS LIABILITY LITIGATION

MDL NO. 2327

THIS DOCUMENT RELATES TO:
ALL CASES IDENTIFIED IN **EXHIBIT A**
TO UNDERLYING MOTION

PLAINTIFFS' REPLY IN SUPPORT OF THEIR TO EXCLUDE OR LIMIT THE OPINIONS AND TESTIMONY OF DR. SALIL KHANDWALA

Plaintiffs hereby submit this *Reply in Support of Their Motion to Exclude or Limit the Opinions and Testimony of Dr. Salil Khandwala*. Defendants filed a response that mischaracterizes Plaintiffs' position, improperly reinterprets the opinions offered by Salil Khandwala, M.D. (hereinafter "Dr. Khandwala") in an attempt to render them admissible, and misstates the applicable law. As such, Plaintiffs respectfully request their Motion be granted in its entirety.

I. ARGUMENT

A. Dr. Khandwala's Methodology is Fundamentally Unreliable and His Opinions on Safety and Efficacy Should be Excluded Accordingly.

To be admissible, an expert must base his testimony upon reliable methodology and reliably apply that methodology to the facts. Fed. R. Evid. 702*; Daubert v. Merrel Dow Pharm., Inc.,* 509 U.S. 579 (1993). Defendants' response simply ignores Dr. Khandwala's unscrupulous methodology of making apples to oranges comparisons between studies, instead arguing that Plaintiffs' challenge is better reserved for cross examination. Defs.' Opp. at 4. This argument represents an attempt to circumvent the Court's role as gatekeeper in determining whether Dr.

Khandwala's testimony is reliable, which forms the basis on which Plaintiffs' challenge his opinions. *See* Defs.' Opp at 3-7. Defendants cite to a number of cases where courts declined to limit testimony based upon an expert's selection or rejection of various studies, Defs.' Opp. at 4-6, but those opinions address the weight to be afforded the evidence, not the critical first step in a *Daubert* analysis – the *methodology* by which an expert forms his or her opinion, *i.e*, whether or not the expert's opinion is reliable. Defendants' cited opinions are therefore inapposite to the challenges Plaintiffs make to Dr. Khandwala's testimony.

Here, Dr. Khandwala's opinions on safety and efficacy are fundamentally unreliable, not because he ignores or emphasizes certain studies, but rather, because he forms his opinions by comparing the success rates of various studies without adjusting the criteria of these studies. *See, e.g., Lee v. City of Richmond*, 2014 WL 5092715, at *18 (E.D. Va. Sept. 30, 2014) (excluding experts' opinion where experts made an "apples to oranges" comparison). Dr. Khandwala forms his opinions on safety and efficacy comparing mesh and native tissue studies without adjusting the results to a uniform, or even similar, criteria with respect to metrics for success. Pls.' Mot. at 3-4. This practice is readily distinguished from ignoring some studies and giving greater weight to others; rather, it comprises a classic "apples to oranges" comparison, constituting a fundamentally unreliable opinion.

The Lin study, highlighted by Plaintiffs, is simply one example of Dr. Khandwala's unreliable methodology.[1] Dr. Khandwala's hysteropexy opinions were highlighted in Plaintiffs'

[1] Defendants assert that Plaintiffs' focus on Dr. Khandwala's reliance upon the Lin study ignores his reliance upon other studies. *See* Defs.' Opp. at 4. However, as noted in Plaintiffs' Motion, while the Lin study is indicative of Dr. Khandwala's unreliable methodology, these problems are pervasive throughout Dr. Khandwala's expert report. *See* Pls.' Mot. at 4-8 (noting methodological problems in Dr. Khandwala's reliance upon the Weber, Ngyuen and Vollebregt studes, as well as pointing to his deposition testimony in which Dr. Khandwala admits that the objective definition of success relied upon in his cited studies is "all over the place"). Moreover, additional examples serve to demonstrate that Dr. Khandwala's methodological problems are in

Motion, not only because the Lin study is the only comparative study relied upon, but also because the study demonstrates Dr. Khandwala's fast and loose approach to native tissue comparisons that renders all of his conclusions suspect. Defendants' argue that "[p]laintiffs have provided no data or documentation showing how their figures were calculated," Defs.' Opp. at 4, in an effort to obfuscate the obvious shortcomings in Dr. Khandwala's methodology. First, Plaintiffs' "recalculations" were completed using basic arithmetic, and were not presented to the Court as an expert opinion in and of themselves, rather, these calculations were presented by Plaintiffs to clearly and simply illustrate the flaws in Dr. Khandwala's methodology. The Lin study attached to Plaintiffs' Motion demonstrates unequivocally that Dr. Khandwala formed his opinion by comparing the results of a 77-subject study to a subsection of only four (4) patients within the Lin study and that the studies utilized disparate criteria. No specialized knowledge is needed to see that the sample size Dr. Khandwala compares his population to is limited to less than a handful of patients and that such comparisons are fundamentally unreliable when the criteria for success, comparatively, is defined differently.

Defendants also fail to substantively address Plaintiffs' argument that Dr. Khandwala selectively ignores subjective measures of success in his safety and efficacy opinions involving native tissue repairs and further argue that there is no scientific basis for giving subjective success metrics greater weight (in a *Daubert* reliability analysis). However, this position is squarely at odds with Dr. Khandwala's "absolute" preference for metrics including subjective

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fact pervasive. Plaintiffs note that Dr. Khandwala's reliance upon the Sivaslioglu report is similarly flawed. *See* Ex. B at 9 n.31. Here, Dr. Khandwala represents that the "mesh group had significantly less abnormal emptying, frequency, urgency, and pelvic pain, and the nonmesh group reported improved symptoms in abnormal emptying and urgency parameters only," *Id.*, despite the fact that in half of the improved-symptom categories with regard to the mesh group, the mesh group started with *more* symptomatic patients pre-surgery, and the authors of the study admitted that the "study population [was] relatively small." Ex. K, Sivaslioglu SS, Unlubilgin E, Dolen I. A randomized comparison of polypropylene mesh surgery with site-specific surgery in the treatment of cystocoele. Int Urogynecol J. 2008; 19:467-471.

criteria. Ex. C at 86:20-87-3. Thus, it is not lack of an independent scientific basis that makes Dr. Khandwala's selective exclusion unreliable (although such an argument could be made), but rather that Dr. Khandwala *ignores his own methodology* where the subjective outcomes of native tissue studies conflict with his opinions regarding the superiority of mesh procedures. This failure to incorporate subjective success metrics where they exist, in spite of the fact that Dr. Khandwala "absolutely" believes subjective measures should be taken into account, as part of his opinions on safety and efficacy goes to the heart of the reliability of his opinions and is distinct from the practice of ignoring or placing greater emphasis on some studies. *See General Elec. Co v. Joiner*, 522 U.S. 136, 146 (1997) (an expert's conclusions and methodology are not "entirely distinct," and where the analytical gap between the data and the opinion proffered is "simply too great," it is within court's discretion to exclude such an opinion); *see also Frankum v. Boston Scientific Corp.*, 2015 WL 1976952, at *13 (S.D. W. Va. May 1, 2015) (excluding opinion of Dr. Blaivis where he employed "less intellectual rigor in forming [his] opinion as an expert witness than he employs when writing studies in his field").

In sum, Dr. Khandwala's practice of cherry-picking objective success metrics within individual studies is fundamentally unreliable because it is inconsistent with reliable methodology and his *own* methodology which "absolutely" incorporates subjective measures in determining successful outcomes. Moreover, this problem, pervasive throughout Dr. Khandwala's expert report (his reliance upon a sample size of four (4) when analyzing the Lin study being just one example) provides an analytical gap that is "simply too great," and therefore his opinions on safety and efficacy should be excluded.

Notwithstanding, Defendants argue that: "Dr. Khandwala in fact addressed subjective outcomes throughout his report," Defs.' Opp. at 5; however, the examples cited by Defendants

contradict this point. Defendants highlight Dr. Khandwala's reliance upon the Hiltunen, Nieminen, and Altman studies as examples of Dr. Khandwala's incorporation of subjective outcomes. *Id.* Yet these studies only demonstrate that Dr. Khandwala ignored the subjective results of these studies where the studies conflict with his preconceived opinions. The Hiltunen study stated: "There were no significant differences between mesh and nonmesh groups in regards to subjective outcomes, such as pelvic pressure or vaginal bulge." Ex. B at 8. The Nieminen study does not appear to have incorporated subjective criteria: ". . . there was a significant difference favoring the mesh group if the optimal outcome was defined as absence of anatomic recurrence . . . ." Ex. B at 9-10 (underscored added). The Altman study's "primary outcome at 1-year follow-up was defined in terms of anatomic success . . . ."[2] Ex. B at 10 (underscore added). Thus, Defendants do not squarely address the fundamental problems inherent in Dr. Khandwala's methodology, *i.e.*, his "apples to oranges" comparisons of objective criteria and his selective disregard for subjective criteria when it contradicts his preconceived conclusions. These methodological problems go beyond "rejecting certain studies, and handling alleged inconsistencies," Defs.' Opp. at 5, and instead demonstrate the inherently unreliable basis for Dr. Khandwala's opinions. As such, Dr. Khandwala's opinions on safety and efficacy should be excluded as unreliable. *See also Hathaway v. Bazany*, 507 F.3d 312 (5th Cir. 2007) ("[w]ithout more than credentials and a subjective opinion, an expert's testimony that 'it is so' is not admissible") (internal citation omitted).

B. Dr. Khandwala's Opinions on Prolift's Safety and Efficacy, Based on His Own Unpublished Study, Should Also be Excluded.

[2] Dr. Khandwala also notes that the Altman study incorporated a "subjective" criteria: "absence of vaginal bulging sensation," Ex. B at 10; however, the absence or nonabsence of vaginal bulging is an objective metric according to Dr. Khandwala. *See* Ex. C at 76:18-21 ("I define . . . subjective success from the patient's standpoint . . . are you bothered by the bulge?").

Dr. Khandwala is not qualified to offer opinions on the safety and efficacy of the Prolift and Prolift+M products. Defendants argue that Dr. Khandwala relied upon "other bases" for his Prolift and Prolift+M opinions; Defs.' Opp at 6, however, this does not change the fact that he *primarily* relied upon his own unpublished study to form the basis of his opinions. Pls. Mot. at 8 ("It's my extensive clinical trial [in answering a question directed at the bases for his safety and efficacy opinions on Prolift] . . . ."). Critically, while Defendants argue the unpublished nature of Dr. Khandwala's study should not be dispositive on the admissibility of his opinions, Defendants fail to note that unlike the circumstances in their cited cases in support of this proposition, here, Defendants are refusing to even provide the data underlying the study which forms the basis for Dr. Khandwala's opinion. Ex. C at 132:20-133:1-6. Thus, it is not just that Dr. Khandwala is primarily relying upon his own unpublished study, but for reasons unknown, Defendants refuse to produce the underlying data from this study to be disclosed. As such, Dr. Khandwala's opinions on the safety and efficacy of the Prolift products are based upon unreliable, indeed unknown data, and therefore these opinions should be excluded. *See Carlson v. Boston Scientific Corp.*, 2015 WL 1931311, at *9 (S.D. W. Va. April 28, 2015) (excluding opinions of Dr. Margolis based on undisclosed sources even when Dr. Margolis cited the undisclosed sources during deposition).

C. Dr. Khandwala's Opinions on Biomaterials, Including Biocompatability, Foreign Body Response, Degradation, Contraction, Porosity, and Stiffness, Should be Excluded.

To the extent Dr. Khandwala's report offers *any* opinion on biocompatibility it is limited to the physical properties of the Prolift and Prolift+M and his opinions on porosity and stiffness. Ex. B at 11-12. At no other point in Dr. Khandwala's report does he even attempt to opine on biocompatibility issues and his testimony reveals his utter lack of qualification to do so. Ex. C at

93:8-94:15; 96:24-97-3. Setting aside his lack of qualification to opine on such issues, Dr. Khandwala's opinions remain fundamentally unreliable and unhelpful to the jury. Defendants concede that Dr. Khandwala is not offering these opinions "from a biomaterials perspective" but rather to inform the jury about the properties of mesh "*from an implanting surgeon's perspective*." Defs.' Opp. at 10 However, Dr. Khandwala's expert report does not make this distinction. Ex. B at 11-12. And critically, Defendants assert "this information is helpful to the jury to understand what physical mesh properties matter to surgeons and why," however, this type of testimony bears the considerable risk of confusing the actual properties the Prolift+M with its "potential" advantages. Defs.' Opp. at 11. This sort of testimony, based on pure conjecture, has no place before the jury. Dr. Khandwala's own testimony reveals that his perception of the "potential" benefits of the Prolift+M is completely speculative, based in part on hearsay from Defendants' employees, and further, that he has seen no clinical difference between the Prolift and Prolift+M in his practice. Ex. C at 124:1-18; 127:10-12; 129:13-15. Dr. Khandwala succinctly summarized the fundamental problems with the bases for his opinions:

> Q. -- the longitudinal, and I'm quoting here, the longitudinal stiffness decreases allowing for the expansion of the neighboring viscera and, hence, potentially decreasing the potential risk of dyspareunia. So I guess what is the basis for that statement?
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> A. So this is what I initially mentioned, when I switched from the Prolift to Prolift+M I think you had asked me why did I make the switch, and I told you that I was clinically hesitant to make the switch because I was enjoying such great results with the Prolift. However, the structural properties of this, you know, ***the potential advantages, potential advantages, the key word is potential***, were enticing enough to make the change in that ***when the engineers told me that the lateral structural integrity of the mesh is preserved,*** that means its support should be good, but once Monocryl disappears, the longitudinal flexibility improves, that means it can stretch better vertically, then, as we mentioned, ***maybe*** that we have a better impact on sexual function, because sexual activity is more longitudinal, as the partner is going inside it's more of a longitudinal movement of the vagina. So then you think intuitively it makes sense. ***Until you actually put it into practice and study it over time, you never know***, you know . . . .

Ex. C 123:15-124:16 (emphases added).

Thus, Dr. Khandwala's testimony has no relevance whatsoever to the inquiry that is before the jury: whether the Prolift+M actually exhibits the properties he describes, even if it has some bearing on what marketing ploys appeal to physicians. Moreover, the potential for prejudice necessitates exclusion. Dr. Khandwala's testimony implies, by virtue of his expertise, that the *potential* advantages of the Prolift+M have some grounding in clinical practice, despite Dr. Khandwala's own testimony that he has seen no such effect. Ex. C at 127:10-12; 129:13-15. This testimony will invariable confuse the "potential" benefits of the Prolift+M with actual, clinically validated results of which there are none that Dr. Khandwala is aware. Accordingly, Dr. Khandwala should be excluded from testifying as to the porosity, stiffness, and biocompatibility of the Prolift and Prolift+M.

With regard to contraction (also referred to as "shrinkage"), Defendants do not actually refute the gravamen of Plaintiffs' argument: Dr. Khandwala's opinions are unreliable. Rather, Defendants argue that Dr. Khandwala's opinions are supported by his clinical experience. This argument ignores the substance of Plaintiffs' argument for exclusion – that observations of mesh's effects on the vagina are not a proxy for the effects of the vagina on mesh. Defendants attempt to obfuscate this Court's inquiry by confusing Dr. Khandwala's opinion that mesh does not contract with a separate opinion that mesh does not cause the vagina to shorten. Ex. B at 16-17. The discrepancies in these two opinions are highlighted by the very literature Dr. Khandwala relies upon, namely the Elmer study, highlighting that measuring vaginal width is a necessary metric to determine whether contraction has occurred. *See generally* Ex. J. Absent a showing that vaginal width did not change following mesh implantation, Dr. Khandwala cannot reliably

demonstrate that mesh did not contract in vivo based *only* upon his clinical observations as a vaginal width measurement is necessary to form this opinion.

Moreover, Dr. Khandwala admits he does not even believe there is a way to measure mesh contraction:

> Q. Okay. So I guess you would agree that contraction or shrinkage of mesh would be an objective type of measurement?
>
> A. Well, first of all, I don't think that, as I've mentioned before, I don't think mesh shrinks, that doesn't happen. So if it doesn't happen, there is no way to measure it.

Ex. C at 117:1-7. As Dr. Khandwala's opinions are formed based on conclusions ignoring requirements for vaginal measurement as stated in his cited study, and more importantly, Dr. Khandwala does not even believe that contraction can be measured at all, his opinions in this regard should be excluded.

Defendants' arguments that Dr. Khandwala's clinical observations support the reliability of his opinions are similarly unconvincing. Dr. Khandwala's testimony that "he has never seen mesh contraction even though he has treated patients for mesh-related complications" is based upon his observations of explanted mesh with the naked eye. Ex. C at 115:7-116:1. These types of unscientific examinations of explants, and opinions extrapolated therefrom, have routinely been excluded by this Court. *See, e.g., Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 554 (S.D. W. Va. 2014) (excluding opinions regarding explanted mesh when opinions based on observations were not derived using "scientific methods"). Therefore, Plaintiffs do not "simply disagree" with Dr. Khandwala's opinions on contractions, but rather, Dr. Khandwala offers unreliable opinions that should excluded.

While Plaintiffs specifically argue that Dr. Khandwala's opinions on foreign body responses, *i.e.*, inflammatory responses, should be excluded, Pls.' Mot. at 11-12, Defendants

provided no opposition to this argument, and therefore, for the reasons provided in Plaintiffs' Motion, these opinions should be excluded. Finally, Defendants concede that Dr. Khandwala will not proffer opinions on degradation or Defendants' IFUs, Defs.' Opp. at 11, and therefore, Plaintiffs' arguments with respect to these issues are likely mooted.

II. CONCLUSION

For the foregoing reasons and the reasons stated in Plaintiffs' Motion, Plaintiffs respectfully request their Motion be granted in its entirety.

Dated: May 16, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on May 16, 2016, a true and correct copy of this *Reply in Support of Their Motion to Exclude or Limit the Opinions and Testimony of Dr. Salil Khandwala*, and exhibits, was served via electronic mail with the Clerk of the Court using the CM/ECF system, which will send notification of such filing to the CM/ECF counsel of record.

/s/ Aimee H. Wagstaff